DM-10/2003

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**
**Re: Appeal to the Board of Patent Appeals and Interferences**

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|---|---|---|---|
| In re Application of: | L. John Teuscher, et al. | Group Art Unit: | 3679 |
| Serial No.: | 10/037,443 | Examiner: | David Bohna |
| Filed: | December 21, 2001 | Our Customer ID: | 22827 |
| For: | Medical Connector | Our Account No.: | 04-1403 |
| Sir: | | Attorney Ref.: | BAL-108 (17451) |



1. [ ] **NOTICE OF APPEAL**: Pursuant to 37 CFR 1.191, Applicant hereby appeals to the Board of Appeals from the decision dated ____ of the Examiner twice/finally rejecting claims _____.
2. [X] **BRIEF** on appeal in this application pursuant to 37 CFR 1.192 is transmitted herewith in triplicate.
3. [ ] An **ORAL HEARING** is respectfully requested under 37 CFR 1.194 (due within one month after Examiner's Answer).
4. [ ] Reply Brief under 37 CFR 1.193(b) is transmitted herewith in triplicate.
5. [ ] "Small entity" verified statement filed: [ ] herewith [ ] previously.
6. **FEE CALCULATION:**

| | Fees |
|---|---|
| If box 1 above is X'd enter $330.00 | $_____ |
| If box 2 above is X'd enter $330.00 | $ 330.00 |
| If box 3 above is X'd enter $290.00 | $_____ |
| If box 4 above is X-d enter –0- (no fee) | $_____ |
| Petition is hereby made to extend the original due date of _____ to cover the date of this paper and any enclosure for which the requisite fee is (1 month $110); (2 months $420); (3 months $950); (4 months $1,480). | $_____ |
| **Subtotal** | $ 330.00 |
| Less any previous extension fee paid since above original due date. | - $_____ |
| **Subtotal** | $ 330.00 |
| If "small entity" box 5 above is X'd, enter one-half (1/2 of subtotal and subtract) | - $_____ |
| **TOTAL FEE** | $ **330.00** |

[X] Fee enclosed.
[X] Charge fee to our Deposit Account/Order Nos. in the heading hereof (for which purpose one additional copy of this sheet is attached)
[ ] Fee NOT required since paid in prior appeal in which the Board of Appeals did not render a decision on the merits.

The Commissioner is hereby authorized to charge any fee specifically authorized hereafter, or any fees in addition to the fee(s) filed, or asserted to be filed, or which should have been filed herewith or concerning any paper filed hereafter, and which may be required under Rules 16-18 (deficiency only) now or hereafter relative to this application and the resulting official document under Rule 20, or credit any overpayment, to our Account No. show in the heading hereof for which purpose a duplicate copy of this sheet is attached. This statement does not authorize charge of the issue fee in this case.

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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| Confirmation No: 4830 | ) | Customer No: 22827 |
| For: Medical Connector | ) | |

## APPEAL BRIEF

Honorable Commissioner of Patents
and Trademarks
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicants hereby submit this Appeal Brief in accordance with 37 C.F.R. § 1.192 for the above-captioned application. The Notice of Appeal was filed on September 16, 2004, in accordance with 37 C.F.R. § 1.8.

Applicants are submitting the filing fee for the filing of the present Appeal Brief as set forth in 37 C.F.R. § 1.17(c).

If any further fee or extension of time is required to obtain entry of the present Appeal Brief, Applicants hereby petition the Commissioner to grant any necessary time extension, and the undersigned hereby authorizes the Commissioner to pay from Deposit Account Number 04-1403, any such fee not submitted herewith.

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## 1. REAL PARTY IN INTEREST:

By assignment recorded on March 1, 2002, at reel 012656, frame 0413, the real party in interest is KIMBERLY-CLARK WORLDWIDE, INC., a corporation of the State of Delaware, whose internal address is 401 North Lake Street, Neenah, Wisconsin 54956.

## 2. RELATED APPEALS AND INTEREFERENCES:

There are no related appeals or interferences.

## 3. STATUS OF CLAIMS:

The application was filed on December 21, 2001 with claims 1-18. Claims 1, 9 and 18 were filed as independent claims.

By Amendment that was mailed on June 4, 2003, claims 1, 9 and 18 were amended.

By Amendment that was mailed on August 29, 2003, claim 9 was amended and claim 10 was canceled.

By Amendment that was mailed on January 30, 2004, claims 1, 9 and 18 were amended.

The claims 1-18 as amended are included in the attached Appendix.

Claims 1-6, 9-15 and 18 stand finally rejected (Advisory Action mailed on August 16, 2004 and the Final Office Action Mailed on May 17, 2004), under 35 U.S.C. § 103(a) as being unpatentable over Lorenzen, et al. '123 (U.S. Patent No. 5,730,123) in view of Webb (U.S. Patent No. 4,676,241) and Linder (U.S. Patent No. 4,774,940). Claims 7 and 16 stand finally rejected under 35 U.S.C. § 103(a) as being unpatentable over Lorenzen, et al. in view of Webb and Linder and further in view of Palmer (U.S. Patent No. 6,494,203). Claims 1-9 and 11-18 also stand finally rejected under 35 U.S.C. §

103(a) as being unpatentable over Palmer in view of Lorenzen, et al. and further in view of Webb and Linder[1]

Applicants appeal all of the final rejections to claims 1-9 and 11-18.

## 4. STATUS OF AMENDMENTS:

A first Final Rejection was mailed in an Office Action on July 25, 2003 (Paper No. 9) rejecting claims 1-18. Applicants mailed an Amendment on August 29, 2003 that amended claim 9 and canceled claim 10 and argued against the rejections to claims 1-18. A first Advisory Action was mailed on September 15, 2003 (Paper No. 11) and a second Advisory Action was mailed on October 14, 2003 (Paper No. 12) but both refused to enter Applicants' Amendment of August 29, 2003. Applicants filed a Request for Continued Examination on October 20, 2003 in order obtain entry of the Amendment mailed on August 29, 2003.

A First Action Final Office Action was mailed on May 17, 2004 rejecting claims 1-9 and 11-18. Applicants mailed a Response on July 20, 2004 in response to the Final Office Action of May 17, 2004 that traversed the rejections to claims 1-9 and 11-18. Applicants' Response was entered into the case by way of a third Advisory Action mailed August 16, 2004 (Paper No. 3), but the final rejection to claims 1-9 and 11-18 was maintained.

## 5. SUMMARY OF THE INVENTION:

The present invention relates to a medical connector that is used in a respiratory circuit that may be attached to the patient in order to perform various medical procedures such as providing oxygen to the lungs of the patient, visual inspection of the

1 The Final Office Action mailed May 17, 2004 and the third Advisory Action mailed August 16, 2004 indicated claims 1-18 were rejected, however claim 10 was canceled in the Amendment mailed August 29, 2003.

respiratory system, elimination of residual carbon dioxide from the lungs, and/or the administration of medication, gases, or lavage to the patient.

Claims 1-9 and 11-18 are drawn generally towards a connector (Reference No. 10 in Figures 1-3 and 6) for a respiratory assembly that includes a body with a first end (Reference No. 12 in Figures 1-3 and 6) and a second end (Reference No. 14 in Figures 1-3 and 6) that each define a single opening. A passage (Reference No. 16 in Figures 1and 6) is disposed through the body from the first end to the second end and allows for the transport of fluids and objects therethrough. The passage changes direction at a single constant angle of approximately 120 degrees between the first end and the second end (see page 3, lines 10-12 of the Specification). The only access to the passage is through the openings of the first and second ends (see Figures 1-3 and 6). Additionally, the first end includes a coupling (Reference No. 62 in Figures 1-3 and 6) that is configured to rotatably engage a first member of the respiratory assembly, and the second end includes a coupling (Reference No. 62 in Figures 1-3 and 6) that is configured to rotatably engage a second member of the respiratory assembly (see page 9, lines 7-23 of the Specification).

It is sometimes the case that a patient who is connected to a respiratory circuit for an amount of time will experience discomfort when the patient moves and pulls on the various tubing or other components of the respiratory assembly (see page 2, lines 8-10 of the Specification). Aside from producing patient discomfort, this pulling could also cause disattachment of various parts of the respiratory assembly or could hamper the flow of fluids therethrough.

The connector (Reference No. 10 in Figures 1-3 and 6) as set forth in claims 1-9

and 11-18 of the present application includes a single constant angle of approximately 120 degrees that allows for a higher degree of patient comfort and for a greater ease of use for the medical caregiver when the connector is incorporated into a respiratory assembly. (see page 8, lines 3-7 of the Specification). Additionally, the ends (Reference Nos. 12 and 14 in Figures 1-6) of the connector, that are configured for rotatable engagement, also allow for a greater degree of patient movement when connected to a respiratory assembly in that associated members of the respiratory assembly will be allowed to move (see page 9, lines 10-16 of the Specification). Further, by providing access to the passageway of the connector through only the openings in the first and second ends, the connector reduces the probability that fluids will leak out of the connector and increases the probability that fluids and surgical instruments will be properly guided through the connector and will not inadvertently escape the connector through an unintended location.

**6. ISSUES:**

Are claims 1-6, 9-15 and 18 obvious under 35 U.S.C. § 103(a) by Lorenzen, et al. in view of Webb and Linder; and are claims 7 and 16 obvious under 35 U.S.C. § 103(a) by Lorenzen, et al. in view of Webb and Linder and further in view of Palmer; and are claims 1-9 and 11-18 obvious under 35 U.S.C. § 103(a) by Palmer in view of Lorenzen, et al. and further in view of Webb and Linder?

**7. GROUPING OF CLAIMS:**

Claims 1-9 and 11-18 rise or fall together.

**8. ARGUMENTS:**

Each of the rejected claims 1-8 and 18 is drawn to a connector that includes:

A body that has a first end that defines a single opening and a second end that defines a single opening;

a passage in the body in which the only access to the passage is through the openings of the first and second ends, the passage changing direction at a single constant angle of 120°.

Each of the rejected claims 9 and 11-17 is drawn to a connector that includes:

A first section that has a first axis and that defines a single opening;

a second section that is connected to the first section and has a second axis and that also defines a single opening;

the connector is configured so that the only access to the first and second passages is through the openings of the first and second sections.

Claim 18 is drawn to a connector that includes:

A body that has a first end that defines a single opening and a second end that defines a single opening, the body having about a 120° constant bend between the first and second ends;

a passage in the body in which the only access to the passage is through the openings of the first and second ends.

**REJECTIONS TO CLAIMS 1-6, 9-15 AND 18**

Claims 1-6, 9-15 and 18 stand finally rejected under 35 U.S.C. § 103(a) by Lorenzen, et al. in view of Webb and Linder.

A1. THE FINAL REJECTION FAILS TO PROVIDE THE REQUIRED SUGGESTION OR MOTIVATION TO COMBINE THE LORENZEN, ET AL., WEBB AND LINDER REFERENCES.

The first criteria that must be met to establish a *prima facie* case of obviousness is that there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine the references. Manual of Patent Examining Procedure, 700-46 (8 Ed. Rev. 2 May 2004). It is necessary to ascertain whether the references' teachings are sufficient for one of ordinary skill in the relevant art having the references before him or her to make the proposed combination. *In re Linter*, 458 F.2d 1013, 1016, 173 U.S.P.Q. 560, 562 (CCPA 1972). In the present case, there is no suggestion or motivation to combine Lorenzen, et al., Webb and Linder as suggested by the Examiner to achieve Applicants' invention as set forth in claims 1-6, 9-15 and 18, and there is no suggestion or motivation generally available to one of ordinary skill in the art to make the proposed combinations and modifications as stated by the Examiner.

Lorenzen, et al. discloses a closed ventilating system that provides an apparatus that accommodates multiple access locations to the respiratory system by providing one or more additional access sites at a proximal adapter port (see the Abstract of Lorenzen, et al.). Access ports 32 and 34 in the adapter of Lorenzen, et al. are provided in order to allow continual cyclic patient ventilation (see Lorenzen, et al. at col. 5, ll. 21-23). A plurality of proximal access ports 34, 36, 38, 40 and 42 allow for multiple access to the respiratory circuit (see Lorenzen, et al. at col. 5, ll. 19-21). Access port 36 allows for irrigation or lavage solution to be administered to the respiratory circuit while access port 38 allows for the insertion of an aspirating catheter (see Lorenzen, et al. at col. 5, ll. 24-31). Access port 40 allows for the introduction of lavage or medication, and access port 42 allows for attachment with an oxygenation catheter assembly (see

Lorenzen, et al. at col. 5, ll. 30-39).

Lorenzen, et al. is specifically directed towards providing multiple access to the respiratory circuit. In order to obtain multiple access to the passageway in the tube adapter 44 of Lorenzen, et al., one or more additional proximal access ports 36, 38, 40 or 42 must be provided in addition to the proximal access port 34 that allows for continual cyclic patent ventilation. Lorenzen, et al. is explicitly directed towards a design that provides multiple access to the passageway between the distal and proximal access ports 32 and 34. Lorenzen, et al. explicitly states that a "lack of equipment to facilely, efficiently and safely accomplish the multiple therapies in the best interests of the patient has been and continues to be a concern" (see Lorenzen, et al. at col. 1, ll. 25-30). Further, Lorenzen, et al. states that it is a "**dominant object**" (emphasis added) of the design in Lorenzen, et al. to provide an apparatus that allows for multiple access to the respiratory system (see Lorenzen, et al. at col. 2, ll. 26-29). Lorenzen, et al. also explicitly states that it is a "**paramount object**" (emphasis added) of the invention in Lorenzen, et al. to provide a closed ventilating system that accommodates multiple access to the respiratory system without compromising the closed character of the system (see Lorenzen, et al. at col. 2, ll. 30-34). In fact, the title of Lorenzen, et al. is "Medical Multiple Access Low Dead Space Anti-Microbial Aspirating/Ventilating Closed System Improvements And Methods." As explicitly stated and stressed in Lorenzen, et al., the entire purpose of the design in Lorenzen, et al. ***is to provide for a system that allows multiple access.***

In the Final Office Action mailed May 17, 2004 the Examiner states on pages 2 and 3 that Webb and Linder demonstrate respiratory tubes in which the only access to

the interior passage is through openings of the first and second ends, and as such it would have been obvious to a person having ordinary skill in the art to make the connector of Lorenzen, et al. have only access to the passage through the openings of the first and second ends because the practice of making respiratory connectors in this fashion is common and well known in the art. However, the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination or modification. *In re Mills*, 916 F.2d 680, 16 U.S.P.Q. 2d 1430 (Fed. Cir. 1990).

In the present case, there is no suggestion in Lorenzen, et al., Webb or Linder to one of ordinary skill in the art to modify Lorenzen, et al. so that the only access to the passageway defined by the distal and proximal access ports 32, 34 is through only the openings of these two ports. Nowhere in these three references is it even hinted that such a modification of a device according to Lorenzen, et al. would be desirable. In contrast, Lorenzen, et al. specifically teaches the desirability of having a plurality of proximal access ports that allow for **multiple** points of access to the passageway defined by the ports 34, 36 in order to provide for an improved apparatus that allows one to aspirate the lungs, oxygenate the lungs, visually inspect the respiratory system, sample gases, monitor flow rates, irrigate the respiratory tract, and/or administer medication. Nowhere in Lorenzen, et al. is it suggested that it would be desirable to remove these points of multiple access and instead reconfigure the passageway so that the only access to the passageway would be obtained through the ports 32 and 34. In fact, Lorenzen, et al. specifically states at several points throughout the disclosure the desirability of having the exact opposite configuration, that is ***allowing for multiple***

***access to the passageway.***

If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 U.S.P.Q. 349 (CCPA 1959). The principle object of the design in Lorenzen, et al. is an adapter that has a multiple access feature. Modification of Lorenzen, et al. in such a way as to remove the essential feature of multiple access would significantly change the principle of operation in Lorenzen, et al. and is not proper.

If the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984). In our case, modifying Lorenzen, et al. so that the passageway defined by the distal and proximal access ports 32, 34 could be accessed only through the access ports 34, 34 would render Lorenzen, et al. unsatisfactory for its intended purpose. This is because such a modification would make it impossible for one to obtain any additional access to the passageway defined by the distal and proximal access ports 32, 34. The resulting apparatus would not be able to allow for multiple access and would therefore be rendered unable to work for its intended purpose.

The exact modification proposed in the Office Action of May 17, 2004 goes completely against the specific teachings of Lorenzen, et al. and would in fact render Lorenzen, et al. incapable of performing in order to achieve the explicitly stated goals of the reference. Lorenzen, et al. does not suggest the desirability or even provide a hint

that would lead one having ordinary skill in the art to modify the device of Lorenzen, et al. so that access to the passageway is obtained only through the ports 32, 34. In fact, Lorenzen, et al. actually teaches one of ordinary skill in the art **not** to provide access solely through the ports 32, 34, but to instead include at least one additional port 36, 38, 40 or 42 through which access may be obtained in order to provide for an apparatus with multiple functionality.

The modification suggested by the Examiner would eliminate a "dominant object" and a "paramount object" of the invention in Lorenzen, et al. and would thus render Lorenzen, et al. unsatisfactory for its intended purpose. Accordingly, there can be no suggestion or motivation to make the proposed modification. Consequently, a case of *prima facie* obviousness in view of Lorenzen, et al., Webb and Linder has not been made.

A2. THE EXAMINER HAS NOT PRESENTED A CONVINCING LINE OF REASONING AS TO WHY THE CONNECTOR SET FORTH IN CLAIMS 1-6, 9-15 AND 18 IS OBVIOUS.

To support a conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the Examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references. *Ex parte Clapp*, 227 U.S.P.Q. 972, 973 (Bd. Pat. App. & Inter. 1985). The Final Office Action mailed May 17, 2004 states that Webb and Linder demonstrate that making respiratory tubes, where the only access to the interior passage is through the openings of the first and second ends, is common and well known in the art. Therefore,

the Examiner reasons that it would have been obvious to a person having ordinary skill in the art to make the connector of Lorenzen, et al. have access to the passage through only the openings of the first and second ends.

However, as previously discussed, and as stated in Applicants' Response of July 20, 2004, Lorenzen, et al. is specifically directed towards an adapter that allows for multiple access of the connector. The Examiner has not presented a convincing line of reasoning as to why one of ordinary skill in the art would decide to go completely against the teachings and intended purpose of Lorenzen, et al. and reconfigure this reference so that the multiple access feature of the connector was removed. Webb and Linder are cited for little more than to show that one or more elements of Applicants' claims in question are known when each of the references is viewed in a vacuum. Claims 1-6, 9-15 and 18 of Applicants' application are directed to a combination of elements and it would not have been obvious for one having ordinary skill in the art to selectively pick and choose elements or concepts from the three cited references when the primary reference of Lorenzen, et al. is specifically directed towards a connector that has a multiple access feature. As such, the Examiner has not presented a convincing line of reasoning as to why it would have been obvious for one to modify Lorenzen, et al. in the manner suggested, and Applicants submit that a case of *prima facie* obviousness has not been made.

A3. THE FINAL REJECTION RELIES ON HINDSIGHT FOR THE ALLEGED MOTIVATION TO COMBINE THE LORENZEN, ET AL., WEBB AND LINDER REFERENCES.

The teaching or suggestion to make the claimed combination and the reasonable

expectation of success must both be found in the prior art and not in Applicants' disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q. 2d 1438 (Fed. Cir. 1991). Absent Applicants' disclosure, there is simply no motivation for one skilled in the art to combine Lorenzen, et al., Webb and Linder in order to arrive at a connector in which access to the passage, or to the first and second passages, is through the openings of the first and second ends, or sections, as set forth in claims 1-6, 9-15 and 18 of Applicants' application. The Examiner has failed to identify any prior art where such a combination is suggested. The only place that the Examiner could have attained the combination of Lorenzen, et al., Webb and Linder is through Applicants' own disclosure. It is impermissible to use Applicants' disclosure as an instruction manual in order to piece together various portions of the prior art so that Applicants' claimed invention is rendered obvious. *In re Fritch*, 972 F.2d 1260, 1266, 23 U.S.P.Q. 2d 1780 (Fed. Cir. 1992).

In making an obviousness determination, to give one of ordinary skill in the art knowledge of the invention, when no prior art references convey or suggest that knowledge, "is to fall victim to the insidious effect of a hindsight syndrome where that which only the inventor taught is used against the teacher." *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1533, 220 U.S.P.Q. 303, 312-13 (Fed. Cir. 1983).

Claims 1-6, 9-15 and 18 of Applicants' application are directed towards a connector that has a new combination of elements. Lorenzen, et al., Webb and Linder do not expressly or impliedly suggest combination with one another in order to obtain Applicants' invention as set forth in the stated claims. The Examiner's stated motivation for combining the references is directly contrary to the specific teachings in the primary

reference of Lorenzen, et al. It would not have been obvious for one having ordinary skill in the art to selectively pick and choose elements or concepts from the various references so as to arrive at the invention set forth in claims 1-6, 9-15 and 18 without using Applicants' own application as a guide to obtain the combination. As stated, hindsight is not a proper criteria for resolving the issue of obviousness and as such, a case of *prima facie* obviousness has not been made.

Therefore, Applicants respectfully submit that claims 1-6, 9-15 and 18 define over the combination of Lorenzen, et al. in view of Webb and Linder as the stated claims are non-obvious

**REJECTIONS TO CLAIMS 1-9 and 11-18**

Claims 1-9 and 11-18 stand finally rejected under 35 U.S.C. §103(a) by Palmer in view of Lorenzen, et al. and further in view of Webb and Linder.

B1. THE COMBINATION OF LORENZEN, ET AL. IN VIEW OF WEBB AND LINDER IS IMPROPER FOR THE REASONS STATED IN SECTIONS A1-A3.

The Final Office Action mailed May 17, 2004 rejected claims 1-9 and 11-18 under 35 U.S.C. § 103(a) by modifying the connector of Lorenzen, et al. in view of Webb and Linder as discussed above and then by using this combination to further modify the primary reference of Palmer. As such, the rejection to claims 1-9 and 11-18 first requires one having ordinary skill in the art to combine Lorenzen, et al. in view of Webb and Linder, and then also requires one having ordinary skill in the art to modify Palmer in view of the combination of Lorenzen, et al., Webb and Linder. It would not have been obvious for one having ordinary skill in the art to combine Lorenzen, et al. in view of

Webb and Linder in the manner suggested by the Examiner for the same reasons as discussed above in sections A1-A3. As such, it naturally follows that it would not have been obvious for one having ordinary skill in the art to modify Palmer in view of the combination of Lorenzen, et al., Webb and Linder because one having ordinary skill in the art would not have available to him or her the combination of Lorenzen, et al., Webb and Linder as such a combination is non-obvious. Therefore, it would have been impossible for one to modify Palmer in the manner stated by the Examiner as the motivation for doing so does not exist.

Additionally, the combination of Lorenzen, et al. in view of Webb and Linder into the primary reference of Palmer results in a multiplicity of references needed in order to render claims 1-9 and 11-18 obvious as claimed. The fact that such a large number of references, in this case four, must be combined to meet claims 1-9 and 11-18 is further evidence of unobviousness.

B2. THE FINAL REJECTION FAILS TO PROVIDE THE REQUIRED SUGGESTION OR MOTIVATION TO MODIFY THE PALMER REFERENCE.

A case of *prima facie* obviousness cannot be made if the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose. *In re Gordon*, 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984). In the present case, to modify Palmer in view of the combination of Lorenzen, et al., Webb and Linder would render the connector of Palmer unsuited for its primary intended purpose and would be directly contrary to the teachings of Palmer.

Palmer discloses an adapter 44 that has a passageway 84 and passageway 86

in communication with one another that are accessed by access ports 32 and 36. As with the connector in Lorenzen, et al., the adapter 44 in Palmer also includes an additional access port 34 that provides access to the passageways 84, 86.

The purpose of the access port 34 in Palmer is to provide for selected insertion and subsequent removal of an aspirating catheter assembly, replacement of residual carbon dioxide with oxygen, temperature measurement, introduction of monitoring instruments, obtaining samples of gases, and/or to allow the insertion of visual inspection instruments (see Palmer at col. 3, ll. 50-58). It is therefore the case that the adapter 44 of Palmer also provides for multiple access to the passageways 84, 86 defined in the access ports 32, 36. In fact, Palmer is specifically directed towards an apparatus in which the "dominant object" of the design is to provide a closed ventilating system that is capable of accommodating multiple access to the respiratory system of a patent (see Palmer at col. 2, ll. 28-31).

Palmer explicitly states that a need exists in finding a way to provide multiple treatments to a patient that may be performed at the same time (see Palmer at col. 1, ll. 26-28). Palmer is stated as meeting this need by providing for an apparatus that accommodates multiple access to the respiratory system (see Palmer at col. 1, l. 67 to col. 2, l. 4). As with Lorenzen, et al., Palmer specifically teaches towards an adapter that provides multiple access to the passageway.

The Final Office Action of May 17, 2004 states that Palmer does not disclose an adapter in which the only access to the first and second passages is through the openings of the first and second sections. The Examiner seeks to modify Palmer upon incorporating the combination of Lorenzen, et al., Webb and Linder so that the only

access to the passageways 84, 86 in Palmer is through the access ports 32, 36. In order to establish a case of *prima facie* obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine the reference teachings. Here, there is no suggestion or motivation present for one of ordinary skill in the art to incorporate the combination of Lorenzen, et al., Webb and Linder into Palmer so as to modify Palmer such that the passageway is accessed only through access ports 32, 36. Nowhere in Palmer is it stated or taught that such a reconfiguration would be desirable. In fact, Palmer discloses the exact opposite in specifically teaching towards a design in which multiple access is provided, and Palmer states that a design with multiple access is desirable over previous types of adapters.

Modification of Palmer in the manner suggested would render this reference unsatisfactory for its intended purpose because the modification would remove the multiple access feature. If the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there can be no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984). In our case, removal of the multiple access feature of Palmer would make the resulting design unsatisfactory because it would not allow for one to access the respiratory tract in the prescribed manner in order to provide suctioning, temperature readings, oxygenation, visual inspection, administration of medicine, etc. It would not have been obvious for one having ordinary skill in the art to modify Palmer because doing so would produce an adapter that would not work for its intended purpose.

The principle of operation in Palmer is having the additional access port 34 be aligned with the passageway 84 in order to accommodate ease of insertion of the slideable aspirating catheter tube 120 (see Palmer at col. 5, ll. 37-43). Modification of Palmer so that the access port 34 was removed, as suggested by the Examiner, would entirely change the principle of operation in Palmer. If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 U.S.P.Q. 349 (CCPA 1959). Modification of Palmer in the manner suggested by the Examiner goes against the direct teachings of Palmer and would defeat the principle of operation in Palmer and as such a case of *prima facie* obviousness of claims 1-9 and 11-18 over Palmer in view of Lorenzen, et al. and further in view of Webb and Linder has not been made.

C1. CONCLUSION

Applicants respectfully submit that independent claims 1, 9 and 18 are patentable over the cited references. If an independent claim is non-obvious under 35 U.S.C. § 103(a), then any claim depending therefrom is non-obvious. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q. 2d 1596 (Fed. Cir. 1988). Claims 2-8 and claims 11-17 are dependent claims that depend either directly or indirectly from independent claims 1 and 9 that are non-obvious under 35 U.S.C. § 103(a). Applicants therefore respectfully submit that claims 1-9 and 11-18 are patentable under 35 U.S.C. § 103(a) in view of the prior art.

Applicants respectfully submit that the Final Rejection of claim 1-9 and 11-18

should be reversed, and that these claims should be allowed to issue in a United States patent.

Respectfully submitted,

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## APPENDIX

## CLAIMS (AS AMENDED) INVOLVED IN APPEAL

1. A connector for a respiratory assembly, comprising:

a body having a first end and a second end, said first end defining a single opening and said second end defining a single opening, said body having a passage disposed therethrough from said first end to said second end to allow for transport of fluids and objects through said body, said passage changing direction at a single constant angle of approximately 120° between said first end and said second end, wherein said first end includes a coupling configured to rotatably engage a first member of the respiratory assembly, wherein said second end includes a coupling configured to rotatably engage a second member of the respiratory assembly, wherein the only access to said passage is through said openings of said first and second ends.

2. The connector for a respiratory assembly of claim 1, wherein the first member is a tracheal tube and the second member is a ventilating tube.

3. The connector for a respiratory assembly of claim 1, wherein said first and second end couplings include hollow female bell housings.

4. The connector for a respiratory assembly of claim 3, wherein:

said first end coupling includes a first sleeve within said bell housing, the entire circumference of said first sleeve is rotatable with respect to said first end so that said first sleeve remains in rotating engagement with said first end, said first sleeve sized for receipt of the first member therein such that said first end rotatably engages the first member; and

said second end coupling includes a second sleeve within said bell housing, the

entire circumference of said second sleeve is rotatable with respect to said second end so that said second sleeve remains in rotating engagement with said second end, said second sleeve sized for receipt of the second member therein such that said second end rotatably engages the second member.

5. The connector for a respiratory assembly of claim 4, wherein:

said first sleeve has a first annular sealing member on one end thereof for engagement with a first annular rib on said first end, engagement between said first annular sealing member and said first annular rib causes deflection of said first annular sealing member to create an essentially hermetic seal between said first sleeve and said first end; and

said second sleeve has a second annular sealing member on one end thereof for engagement with a second annular rib on said second end, engagement between said second annular sealing member and said second annular rib causes deflection of said second annular sealing member to create an essentially hermetic seal between said second sleeve and said second end.

6. The connector for a respiratory assembly of claim 5, wherein:

said first and second ends each having a stepped annular ring; and

further comprising a first and second retainer disposed in said respective annular rings for retaining said first and second sleeves in engagement with said respective first and second ends.

7. The connector for a respiratory assembly of claim 1, wherein said body, said first end, and said second end are plastic, are made by injection molding, and are substantially transparent.

8. The connector for a respiratory assembly of claim 1, wherein the first member is a tracheal tube and the second member is a humidifier tube.

9. A connector for a respiratory assembly, comprising:

a first section being substantially cylindrical in shape, said first section having a first axis, said first section defining a single opening, said first section having a first passage therethrough to allow for transport of fluids and objects through said first section, said first section rotatably engageable with a first member of the respiratory assembly;

a second section being substantially cylindrical in shape and being connected to said first section, said second section having a second axis, said second section defining a single opening, said second section having a second passage therethrough in communication with said first passage to allow for transport of fluids and objects through said second section, said second section rotatably engageable with a second member of the respiratory assembly; and

wherein a single constant angle of about 120° exists between said first axis and said second axis;

wherein the only access to said first and second passages is through said openings of said first and second sections.

10. (Canceled)

11. The connector for a respiratory assembly of claim 9, wherein the first member is a tracheal tube and the second member is a ventilating tube.

12. The connector for a respiratory assembly of claim 9, wherein said first and second sections have hollow female bell housings.

13. The connector for a respiratory assembly of claim 12, further comprising:

a first sleeve within said bell housing in said first section, the entire surface of said first sleeve is rotatable with respect to said first section so that said first sleeve remains in rotating engagement with said first section, said first sleeve sized for receipt of the first member therein such that said first section rotatably engages the first member; and

a second sleeve within said bell housing in said second section, the entire surface of said second sleeve is rotatable with respect to said second section so that said second sleeve remains in rotating engagement with said second section, said second sleeve sized for receipt of the second member therein such that said second section rotatably engages the second member.

14. The connector for a respiratory assembly of claim 13, wherein:

said first sleeve has a first annular sealing member on one end thereof for engagement with a first annular rib on said first section, engagement between said first annular sealing member and said first annular rib causes deflection of said first annular sealing member to create an essentially hermetic seal between said first sleeve and said first section; and

said second sleeve has a second annular sealing member on one end thereof for engagement with a second annular rib on said second section, engagement between said second annular sealing member and said second annular rib causes deflection of said second annular sealing member to create an essentially hermetic seal between said second sleeve and said second section.

15. The connector for a respiratory assembly of claim 14, wherein:

said first and second sections each having a stepped annular ring; and

further comprising a first and second retainer disposed in said respective annular rings for retaining said first and second sleeves in engagement with said respective first and second sections.

16. The connector for a respiratory assembly of claim 9, wherein said first and second sections are plastic and are substantially transparent, said first and second sections are made by injection molding.

17. The connector for a respiratory assembly of claim 9, wherein the first member is a tracheal tube and the second member is a humidifier tube.

18. A connector for a respiratory assembly, comprising:

a body having a first end defining a single opening and a second end defining a single opening, said body having a passageway for the transport of fluids and objects through said body, said body having about a 120° single constant bend between said first end and said second end, wherein the only access to said passageway is through said openings of said first and second ends;

a first female bell housing connected to said first end having a first annular rib;

a second female bell housing connected to said second end having a second annular rib;

a first sleeve disposed within said first female bell housing, said first sleeve having a first annular sealing member configured to engage said first annular rib and effect a hermetic seal between said passageway and the outside of the respiratory assembly;

a second sleeve disposed within said second female bell housing, said second

sleeve having a second annular sealing member configured to engage said second annular rib and effect a hermetic seal between said passageway and the outside of the respiratory assembly;

wherein said first sleeve is adapted to engage a first member of the respiratory assembly and permit rotational motion between said body and the first member of the respiratory assembly; and

wherein said second sleeve is adapted to engage a second member of the respiratory assembly and permit rotational motion between said body and the second member of the respiratory assembly.